REMARKS

Claims 1, 2, 8, 9, 17, and 18 are pending and stand rejected. Applicant respectfully requests reconsideration of the present application in view of the remarks below.

Claim Objections

The Examiner objects to claim 1 stating that the phrase "an afferent portion" appears twice in line 3. Applicant respectfully points out that there is no mistake and that the words "afferent" and "efferent," which appear in claim 1, line 3, have two different meanings.

Rejections Pursuant to 35 U.S.C. §103(a)

Claims 1 and 2 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,669,680 of Macoviak, et al. Claims 8, 9, 17, and 18 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Macoviak, et al., in view of U.S. Patent No. 3,802,432 of Djerassi, et al., and U.S. Patent No. 6,048,333 of Lennox, et al.

Obviousness Rejection of Claims 1 and 2

With regard to claims 1 and 2, Applicant submits that Macoviak does not teach or even suggest the claimed hub assembly, seal, and inflow ports. The Examiner refers to FIG. 11 of the Macoviak patent arguing that it discloses "[a] perfusion catheter system for selectively and temporarily delivering perfusion fluid to a branch vessel originating from a host structure having an elongate body with an efferent end portion, a lumen extending therebetween for passage of fluid therethrough; an inflow port at the afferent end portion in communication with the lumen and being configured to be coupled to a perfusion source to receive perfusion fluid, and a hub assembly defining an outflow port at the efferent end portion in communication with the lumen to deliver the perfusion fluid to the branch vessel, the branch assembly being configured for placement over the origin of the branch vessel, wherein the hub assembly provides a water-tight seal with a inner surface of the host structure adjacent the origin of the branch vessel."

Claim 1 of the present invention recites a perfusion catheter system for selectively and temporarily delivering perfusion fluid to a branch vessel originating from a host structure. The catheter system includes an elongate body having an efferent end portion, an afferent end portion, and a lumen extending therebetween for passage of fluid therethrough. Further, an inflow port at the afferent end portion must be in communication with the lumen and be configured to be coupled to a perfusion source to receive perfusion fluid. Claim 1 also requires a hub assembly defining an outflow port at the efferent end portion in communication with the lumen to deliver the perfusion fluid to the branch vessel, and the hub assembly must be configured for placement over the origin of the branch vessel. The hub assembly is required to provide a water-tight, atraumatic seal with an inner surface of the host structure adjacent the origin of the branch vessel.

Applicant respectfully disagrees with the Examiner's characterization of the Macoviak disclosure. Macoviak merely teaches a single catheter shaft having at least three lumens therein, and a flow divider attached to the distal end of the catheter shaft. The flow divider is a passive baffle that is placed in an artery to re-direct only some of the flow of blood around the catheter shaft. The flow divider does not create any type of water-tight seal between any part of the catheter shaft and an inner surface of the host structure adjacent the origin of a branch vessel. In fact, Macoviak even states that a seal is not critical because pressure gradients within the artery will minimize the flow around the edges of the flow divider. (See, Macoviak col. 9, line 40-45.) This configuration results in the flow divider moving within the artery in accordance with changes in blood flow and blood pressure such that the flow divider repeatedly strikes the artery walls, potentially damaging the artery wall. In contrast, the claimed invention utilizes a hub structure which creates an atraumatic seal adjacent the origin of a branch vessel.

A further deficiency in Macoviak is that it fails to disclose or suggest a hub assembly as required by claim 1. As noted above, claim 1 requires a hub assembly that defines an outflow port at the afferent end portion of the catheter. The hub assembly must be configured for placement over the origin of the branch vessel, and it must provide a water-tight, atraumatic seal with an inner surface of the host structure adjacent the origin of the branch vessel. The

Macoviak catheter does not disclose or suggest any such hub structure. The fact that Macoviak's design does not rely on a water-tight seal to effect perfusion provides evidence of the stark differences between it and the claimed invention and precludes any argument that Macoviak could even suggest a perfusion catheter system as claimed.

Although the Examiner recognizes that Macoviak does not expressly describe an atraumatic seal, he argues that such a seal is "inherent" to the structure disclosed by Macoviak. Applicant respectfully disagrees. As described above, any seal created in the Macoviak device depends on the flow divider pressing against the aortic arch wall as a result of higher positive pressure on the lower side of the flow divider. Because this structure achieves only intermittent contact, as a result of fluctuations in blood pressure, there is no seal. After all, each time pressure drops, the flow divider will lose contact with the aortic arch and fluid flow will be permitted.

Accordingly, Macoviak does not teach or even suggest the claimed perfusion device, and therefore claim 1 distinguishes over Macoviak and represents allowable subject matter. Claim 2, is allowable at least because it depends from claim 1 and contains all limitations thereof.

Obviousness Rejection of Claims 8 and 9

Claims 8 and 9 are rejected as being obvious over Macoviak in view of Djerassi and Lennox. Applicant respectfully traverses this rejection.

Claims 8 and 9 include all limitations of claim 1 and therefore distinguish over Macoviak for the reasons indicated above. Djerassi and Lennox, alone or in combination, fail to remedy any of the many deficiencies of Macoviak. Accordingly, the rejection of these claims must be withdrawn.

Obviousness Rejection of Claims 17 and 18

Claims 17 and 18 are also rejected as being obvious over Macoviak in view of Djerassi and Lennox. Ignoring the other deficiencies of Macoviak, the Examiner admits that the Macoviak patent does not "disclose the use of a vacuum source to remove substances from the body via catheter." However, the Examiner argues that Lennox remedies this defect stating that Lennox demonstrates the use of a vacuum source to remove substances from the human body. The Applicant respectfully traverses this rejection.

Claim 17 is directed to a perfusion device for selectively and temporarily delivering perfusion fluid to a branch vessel originating from a host structure. The perfusion device must have an elongate body having an efferent end portion, an afferent end portion, and a lumen extending therebetween for passage of fluid therethrough, wherein the afferent end portion is configured to be coupled to a perfusion source to receive perfusion fluid. The device must also have a hub extending from the efferent end portion and being in communication with the lumen to deliver the perfusion fluid to the branch vessel. The hub must be surrounded by a conformable concave contact ring adapted for placement over the origin of the branch vessel. Further, the device must have a suction channel extending through the elongate body and having a connector port for coupling with a vacuum source. The suction channel must be in communication with the conformable concave contact ring for applying a vacuum pressure such that the conformable concave contact ring forms a water tight, atraumatic seal between the hub and the host structure of the branch vessel.

The Macoviak reference fails to disclose or suggest several elements that are present in claim 17. In particular, Macoviak fails to disclose or suggest a hub or a suction channel. Macoviak's deficiencies in failing to disclose a hub are noted above with respect to claim 1. The Djerassi and Lennox references likewise fail to disclose or suggest any such hub in a perfusion device, alone or in combination with each other. The Examiner evidently recognizes these shortcomings of the secondary references since he never claims that such a hub assembly is disclosed.

Regardless of whether the Lennox reference discloses any type of suction channel is irrelevant because it does not disclose or suggest "a suction channel extending through the elongate body and having a connector port for coupling with a vacuum source, the suction channel being in communication with the conformable concave contact ring for applying a vacuum pressure such that the conformable concave contact ring forms a water tight, atraumatic seal between the hub and the host structure of the branch vessel" as required by claim 17. The use of a vacuum source in Lennox is solely for the purpose of evacuating blood from a vessel to isolate a part of the vessel's volume in order to repair an aneurysm. There is simply no suggestion in Lennox or in any other cited reference to provide a suction channel extending through the elongate body and having a connector port for coupling with a vacuum source, such that the suction channel is in communication with the conformable concave contact ring for applying a vacuum pressure such that the conformable concave contact ring forms a water-tight, atraumatic seal between the hub and the host structure of the branch vessel.

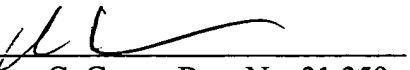
Accordingly, Macoviak, alone or in combination with either or both of Djerassi or Lennox, does not teach or even suggest the device required by claim 17. Claim 17 therefore distinguishes over these references and represents allowable subject matter. Claim 18 is allowable at least because it depends from claim 17 and contains all limitations thereof.

Conclusion

In view of the remarks above, Applicant submits that claims 1, 2, 8, 9, 17, and 18 are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

Date: August 31, 2004



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